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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/894,788	08/27/1997	PAOLO GIACOMONI	05725.0213	9346
22852	7590	07/29/2005	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			CHANNAVAJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/894,788

Applicant(s)

GIACOMONI, PAOLO

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-38, 40-54 and 56-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-38, 40-54 and 56-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5-17-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the decision rendered by Board of Appeals and Interferences, the finality of the rejection of the last Office action is withdrawn.

The following rejection new rejection is applied:

Claim Rejections - 35 USC § 103

Claims 31-38, 40-54 and 56-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,951,990 (hereafter '990) to Ptchelintsev by itself or US 5,847,003 to Ptchelintsev et al (hereafter '003).

'990 teach a composition comprising a derivative of L-ascorbic acid, which is stable, easily incorporated into cosmetically acceptable vehicles and suggest preparing the composition in the form of lotions, gels, creams etc 9col. 5). '990 teach using the ascorbic acid derivative of cholesterol with other cosmetically active agents such as retinoids, alpha-hydroxy and beta-hydroxy acids, vitamin D (col. 6) etc., all of which read on the claimed irritant compounds in the instant invention. '990 further teaches that the compositions containing ascorbic acid derivatives can be used in combination with nitric oxide synthase inhibitors such as those claimed in the instant application (col. 8, lines 41-59). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare a composition comprising the claimed nitric oxide synthase inhibitors, together with ascorbic acid derivatives and cosmetic compounds such as retinoids, alpha-hydroxy and beta-hydroxy acids, vitamin D etc.,

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which are capable of causing cutaneous irritation, because '990 suggests that the NO synthase inhibitors reduce skin redness, vasodilation and inflammatory reactions, especially in response to electromagnetic and ionizing radiation and or to the action of chemically or biochemically aggressive compounds. Further, '990 suggest the amounts of the NO synthase inhibitors useful for the above treatment and accordingly using the optimum amounts of the same so as to obtain the desired effect would have been within the scope of a skilled artisan.

'003 teach a composition comprising oxa acids and their derivatives for treating skin conditions such as psoriasis, eczema, dry skin etc (col. 2). '003 teach formulations containing oxa acids gels, creams (examples) and suggest using skin treating compounds such as alpha-hydroxy and beta-hydroxy acids in the composition. Examiner notes that the latter compounds read on the claimed irritants. '003 also suggest combining oxa acids with vitamins, retinoids etc (col. 5), depending on the dermatological treatment desired. Further, '003 teach addition of NO synthase inhibitors that read on the instant claims, to the compositions containing oxa acids (col. 9, lines 40-60). Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use NO synthase inhibitors of '003 in compositions containing oxa acids and other vitamins, retinoids or alpha-hydroxy and beta-hydroxy acid because '003 suggests that the NO synthase inhibitors reduce skin redness, vasodilation and inflammatory reactions, especially in response to electromagnetic and ionizing radiation and or to the action of chemically or biochemically aggressive

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compounds. Further, '003 suggest the amounts of the NO synthase inhibitors useful for the above treatment and accordingly using the optimum amounts of the same so as to obtain the desired effect would have been within the scope of a skilled artisan.

Claims 31-38, 40-54 and 56-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,449,688 to Wahl et al ('688) in view of either of US 5,951,990 ('990) to Ptchelintsev or US 5,847,003 to Ptchelintsev et al ('003).

'688 teach treatment of chronic inflammatory conditions such as psoriasis (paragraph bridging cols. 3 and 4), by administering the specific nitric oxide synthase inhibitors of the instant claims (see col. 3, lines 39-68). '688 teach dosages, several routes of administration, including topical application (col. 4, lines 25-54; col. 6, lines 53-65). '688 teaches the same skin conditions, which have a predisposition to be irritated upon exposure to common cosmetic and pharmaceutical products and suggests topical application of nitric oxide synthase inhibitors. However, '688 do not specifically teach the inhibitor compounds as anti-irritants and also fails to suggest a combination of irritants together with the compositions. '688 teach topical application as transdermal patches but do not teach the composition in the form of gel or cream.

The teachings of '990 and '003 have been discussed above. '990 and '003 suggest a combination of skin care compounds such as ascorbic acid derivatives ('990) and oxa acids ('003) with alpha or beta hydroxy acids, retinoids, vitamins etc., all of

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them are admittedly capable of causing cutaneous irritation. Further '990 and '003 teach addition of claims nitric oxide synthase inhibitors to the above compositions for reducing skin redness, vasodilation etc. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use NO synthase inhibitors of '688 in topical cosmetic or dermatological composition comprising retinoids, vitamins, oxa acid, ascorbic acid etc., because '990 and '003 teach that the NO synthase inhibitors are capable of reducing skin redness, vasodilation and inflammatory reactions, especially in response to electromagnetic and ionizing radiation and or to the action of chemically or biochemically aggressive compounds. Thus, a skilled artisan would have expected to reduce the irritation, redness, and inflammation etc., caused by aggressive chemicals present in the cosmetic compositions (such as those of '990 and '003).

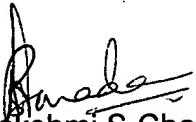
Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lakshmi S Channavajjala
Examiner
Art Unit 1615
July 28, 2005


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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